PODIUM SESSION II: CARDIOVASCULAR DISEASE OUTCOMES RESEARCH

CV1

COST-EFFECTIVENESS OF A NURSE FACILITATED SELF-MANAGEMENT PROGRAMME FOR HEART FAILURE

Mejia A[1], Richardson G[2], Cockayne S[2], Pattenden J[2], Lewin R[2]
[1]Universidad de Antioquia, Medellín, Antioquia, Colombia, [2]University of York, York, UK

OBJECTIVES: To assess the cost-effectiveness of a nurse facilitated, cognitive behavioural self-management programme for patients with heart failure compared with usual care including the un-facilitated access to the same manual, from the perspective of the NHS. **METHODS:** Data were obtained from a pragmatic, multicentre, randomised controlled 'open' trial conducted in seven centres in the UK between 2006 and 2008. Effectiveness was estimated as Quality-Adjusted Life Years. Resource use was measured prospectively on all patients using information provided by patients in postal questionnaires, case-note review, electronic record review and interviews with patients. Unit costs were obtained from the literature and applied to the relevant resource use to estimate total costs. Multiple imputation was used to handle missing data. **RESULTS:** There were no substantial differences in the utility scores between treatment groups in all follow-up assessments, in the use of medication or outpatient visits and both groups report a similar frequency of contact with health care professionals. After controlling for baseline utility and using imputed dataset, treatment was associated with a reduction in QALY of 0.004 and a reduction in costs of £116.2, generating an incremental cost-effectiveness ratio of £29,036 for usual care. The probability that the intervention is cost-effective for thresholds between £20,000 and £30,000 is around 60%. **CONCLUSIONS:** There is little evidence that the addition of the intervention had any effect on costs or outcomes. The uncertainty around both estimates of cost and effectiveness mean that it is not reasonable to make recommendations based on cost-effectiveness alone.

CV2

IS IT WORTH SPENDING ANY MONEY TO DEVELOP A BIOMARKER TEST TO OPTIMIZE STATIN TREATMENT FOR INDIVIDUALS WITH AN INTERMEDIATE CARDIOVASCULAR RISK?

Burgers LT[1], Nauta ST[2], Deckers JW[2], Severens JL[1], Redekop WK[1]
[1]Erasmus University Rotterdam, Rotterdam, The Netherlands, [2]Erasmus Medical Center, Rotterdam, The Netherlands

OBJECTIVES: The 2012 European guideline on cardiovascular disease prevention recommends statin therapy for individuals with elevated cholesterol levels and with an intermediate risk of fatal events. However, since many individuals fall into this category, improved discrimination is needed to prevent both cardiovascular disease (CVD) and statin side-effects (e.g. myopathy) efficiently. We estimated the potential cost-effectiveness of a novel biomarker test which helps to decide which individuals with an intermediate risk should receive statins. **METHODS:** Prognosis of different age- and gender-specific cohorts with an intermediate risk was simulated with a literature-based Markov model to estimate the potential costs and quality-adjusted life-years (QALYs) for four strategies: treat all with statins, treat none with statins, treat according to the European guideline or use a test to select individuals for statin treatment. Costs were calculated for the Netherlands using a health care sector perspective. **RESULTS:** The test-first strategy was the least expensive strategy as long as a perfect test cost no more than €304 at a threshold of €20000 per QALY gained. The perfect test-first and treat-all strategy reduced the same number of events leading to comparable QALYs but the test generated lower medication and drug side-effect costs. The treat-none strategy was the least cost-effective strategy. The test needs to be very accurate and inexpensive in order to be the most cost-effective strategy, since the impact of myopathy on cost-effectiveness is negligible and statin costs are low. **CONCLUSIONS:** A test that improves treatment decisions for individuals with an intermediate CVD risk has the potential to optimize cost-effectiveness by reducing the risk of drug side-effects and budget impact. However, given the outcomes of this 'early stage' cost-effectiveness analysis there may be limited value in developing a test with this indication. Early stage economic evaluations can assist industry in determining whether a test is worth developing.

CV3

OUTCOMES AND COSTS OF CONCOMITANT AORTIC VALVE REPLACEMENTS ASSOCIATED WITH A NEW SUTURELESS AND COLLAPSED VALVE IN ITALY, FRANCE, GERMANY, AND THE UK

Pradelli L[1], Zaniolo O[1], Giardina S[2], Ranucci M[3]
[1]AdRes HE&OR, Turin, Italy, [2]Sorin Group, Saluggia, Italy, [3]IRCSS Policlinico San Donato, San Donato Milanese, Italy

OBJECTIVES: Aortic valve replacement (AVR) is the most common heart valve operation, accounting for a conspicuous part of all valve surgery performed in the elderly. A significant subset of patients with indications for valve surgery are deemed ineligible for conventional valve replacement because of high-risk features or age. Prolonged aortic cross-clamping times (CCT) are an independent risk factor for worse outcomes. Perceval S is a new aortic valve which is implanted without need for suturing and a collapsed profile, thus allowing a significant reduction of cross-clamping times. Aim of this simulation study was to predict costs and outcomes of concomitant AVR procedures associated with this new valve in 4 European countries (Italy, France, Germany, and UK), as compared to traditional valve implants, from the cost perspective of the hospital. **METHODS:** A probabilistic, patient-level simulation model was fully coded in WinBugs, permitting a seamless integration of parameter estimation and outcomes prediction, which was entirely based on the associated CCTs, through published correlations. Unit cost were retrieved from official and literature sources for all countries. Besides the incorporated probabilistic sensitivity analysis, a series of deterministic sensitivity analyses was performed. **RESULTS:** The model predicts less complications with the use of the Perceval S valve, and savings (valve cost excluded) ranging from about 6,000 € (Italy) to about 6,700 £ (UK), mainly related to a reduction in surgery costs and ICU/hospital bed days. Extensive sensitivity analyses confirm the robustness of such findings. **CONCLUSIONS:** Reduced cross clamping times associated with the implantation of Perceval S result in relevant savings on surgical, complication managment and hospital stay costs in all analysed settings.

CV4

EVALUATION OF TELEMONITORING FOR HEART FAILURE PATIENTS WITH IMPLANTABLE DEFIBRILLATORS: THE EVOLVO (EVOLUTION OF MANAGEMENT STRATEGIES OF HEART FAILURE PATIENTS WITH IMPLANTABLE DEFIBRILLATORS) STUDY

Zanaboni P[1], Marzegalli M[2], Landolina ME[3], Lunati M[4], Perego GB[5], Guenzati G[2], Curnis A[6], Borghetti F[7], Beccagutti G[7], Borghi G[8], Masella C[9]
[1]Politecnico of Milano/University Hospital of North Norway, Milano, Italy, [2]San Carlo Borromeo Hospital, Milano, Italy, [3]San Matteo Hospital, Pavia, Italy, [4]Niguarda Hospital, Milano, Italy, [5]S. LUCA Hospital - IRCCS, Milano, Italy, [6]Spedali Civili, Brescia, Italy, [7]Medtronic Italia, Sesto San Giovanni, Italy, [8]CEFRIEL, Regione Lombardia, Milan, Italy, [9]Politecnico of Milano, Milano, Italy

OBJECTIVES: Heart failure patients with implantable defibrillators (ICD) frequently undergo in office visits, placing a great burden on health care providers. Internet-based remote device interrogation systems are being proposed in order to reduce these visits, as well as to promptly detect and notify alert conditions. **METHODS:** EVOLVO was a prospective, randomized, parallelmulticenter clinical trial comparing remote ICD management with the current standard of care, assessing their effectiveness and costs.Primary end-point: rate of cardiac or device related unplanned emergency department (ED) or urgent in-office visits. Secondary endpoint: all health care utilizations for HF, arrhythmias or device related events; quality of life (QoL), assessed with the Minnesota Living with Hearth Failure Questionnaire (MLHFQ), and EuroQol five Dimensions (EQ 5D). Costs were considered from National Health Services (NHS) and patients' and society point of view. **RESULTS:** Two hundred patients (79% males; 66±10years) implanted with ICD (92% biventricular ICD) were enrolled in five Hospitals in Italy, with a follow-up of 16 months.The rate of visits considered in primary endpoint was reduced by 36% in remote arm (75 versus 117; Incidence density: 0.59 versus 0.93 events/year; p=0.005). Overall, there were 1285 health care utilizations (secondary endpoint) with a difference of 23% in the rates of events (4.40 events/year in remote arm vs 5.74 events/year in standard arm).The telemonitoring implied annual cost saving per patient-year for NHS: €1962.78 for remote arm versus €2130.01 for the standard arm. Further, remote arm gained 0.065 QALYs per patient vs standard arm. From patients and society point of view, a cumulative costs per patient-year of 154 € (standard arm) versus 112 € (remote arm) was assessed. **CONCLUSIONS:** Remote management of chronic heart failure patients with ICD is a cost-effective solution, with clinical and economic benefits for both health care systems and patients. A large-scale adoption should be supported.

PODIUM SESSION II: MEDICATION ADHERENCE RESEARCH

MA1

UTILIZATION OF DISEASE MODIFYING AGENTS IN MULTIPLE SCLEROSIS: ANALYSIS FROM AN ITALIAN ADMINISTRATIVE DATABASE

Furneri G[1], Scalone L[2], Ciampichini R[1], Cortesi PA[2], Fornari C[2], Madotto F[2], Chiodini V[2], Cesana G[2], Mantovani LG[3]
[1]Charta Foundation, Milan, Italy, [2]University of Milano - Bicocca, Monza, Italy, [3]Federico II University of Naples, Naples, Italy

OBJECTIVES: To assess patients' adherence and patterns of drug utilization through administrative database analysis. **METHODS:** Using DENALI datawarehouse we detected all MS patients who, during the period January 2000 – December 2009, had at least one DMA prescription (IFN beta-1a intramuscular (IM); IFN beta-1a sub-cutaneous (SC) at two different dosages: 22mcg and 44mcg; IFN beta-1b, glatiramer acetate, natalizumab). Three drug utilization indicators, probability of switching therapy, density of medication possession ratio (DMPR) and drug persistence (measured with Kaplan-Meier method) were calculated to measure DMAs' usage. Patients were grouped according to first DMA prescription, with the date of first prescription being the index date. **RESULTS:** A total of N=5,099 subjects received at least one DMA prescription. Switching therapy occurred in 393 of 1,391 patients initiating with IFN beta-1a IM (28.3%), 482 of 964 IFN beta-1a SC 22mcg patients (50.0%), 192 of 605 IFN beta-1a SC 44mcg patients (31.7%), 150 of 886 IFN beta-1b patients (16.9%), 205 of 1,200 glatiramer acetate patients (17.1%), and 2 of 53 natalizumab patients (3.8%) with glatiramer acetate, 4% with natalizumab. Median times to switch ranged from 1.8 to 2.5 years. Adherence rates were high: percentage of patients achieving DMPR>80% ranged from 78.1% to 88.9%. Probability of drug persistence was, on average, about 80% at the end of first year of observation, being similar across different treatments. **CONCLUSIONS:** Patients tend to adhere quite well to prescribed DMA medication. However, a relevant number of patients receive therapy adjustment or modification in the short term period (after about two years of treatment), maybe because of lack of efficacy or adverse events occurrence, both factors discouraging or impeding continuation. DENALI shows to be an efficient instrument to assess prescription patterns of DMAs, although linkage with clinical registries would remain necessary to assess reasons of switch/drop out, and to evaluate DMAs' efficacy.